DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0283]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

The generic Animal Drug and Patent Term Registration Act of 1988 permitted generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based in part upon a demonstration of bioequivalence between the generic product and pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence by the stature does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s), is the same as the pioneer product, is soluble , and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form

products and Type A medicated articles, solubility can be demonstrated in two ways: "USP definition" approach or "Dosage Adjusted" approach.

In the **Federal Register** of August 3, 2004 (69 FR 46553), the agency requested comments on this collection of information. In response to that notice, the agency received several comments on the guidance, two from individuals who were generally favorable and one from the Animal Health Institute (AHI), which was supportive of some aspects of the proposed guidance and not supportive of others. None of the comments received took issue with any aspect of the paperwork burden associated with the draft policy. The Center for Veterinary Medicine has revised the substance of the proposed guidance in several respects in response to AHI comments.

The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in tables 1 and 2 of this document. The source of the data is records of generic drug applications over the past 10 years.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS[1]

	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
Same Formulation / Manufacturing Process Approach	1	1	1	5	5
Same API / Solubility Approach	5	5	5	10	50
Total Burden Hours					55

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]

	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hourse per Response	Total Hours
Same Formulation / Manufacturing Process Approach.	2	2	2	5	10
Same API / Solubility Approach	10	10	10	20	200
Total Burden Hours					210

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: OCT 17 2005

October 17, 2005.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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